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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,721	09/22/2003	Sek Chuen Chow	GJE-73D1	9693

23557 7590 12/13/2005

SALIWANCHIK LLOYD & SALIWANCHIK  
A PROFESSIONAL ASSOCIATION  
PO BOX 142950  
GAINESVILLE, FL 32614-2950

EXAMINER

WARE, DEBORAH K

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 12/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/667,721

Applicant(s)

CHOW-ET AL.

Examiner

Deborah K. Ware

Art Unit

1651

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) 2-5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1-6 are pending.

#### ***Election/Restrictions***

Applicant's election without traverse of Group I in the reply filed on January 12, 2005, is acknowledged.

Claims 2-5 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention(s), there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on January 12, 2005.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### ***Response to Amendment***

The amendment and remarks filed September 28, 2005, have been received and entered. Also the extension of time filed September 28, 2005, has been received. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Specification***

The specification is objected to because the parent case status has not been updated. Applicants are requested to update the status of the parent application 09/889,256 filed August 27, 2001, which is now abandoned.

***Claim Rejections - 35 USC § 102***

Claims 1 and 6 remain rejected under 35 U.S.C. 102(e) as being anticipated by newly cited Dopheide et al, cited of record in the last office action of March 29, 2005.

Claims are drawn to product and composition wherein the product is an excretory-secretory product from *Necator americanus* and is less than 12 kDa. The composition comprises the product and a carrier and the product is less than 12 kDa.

Dopheide et al teach a first embodiment wherein an excretory/secretory product is derived from (see column 6, lines 45-47 and column 7, line 3) *Necator americanus*. The product is further disclosed to be less than 12 kDa wherein at column 6, line 58 the molecular weight for the product is 11 kDa. Further, at column 9, lines 29-38, there is disclosed a fourteenth embodiment which discloses a composition comprising the product and a carrier and/or diluent, see column 9, line 35.

The claims are identical to the cited disclosure and are therefore, considered to be clearly anticipated by the teachings of this cited reference.

***Response to Arguments***

Applicant's arguments filed November 28, 2005, have been fully considered but they are not persuasive. The argument that the prior art does not disclose applicants' advantageous composition that induces apoptosis in reactive T-cells is noted. However, at column 6, lines 47-49, the excretory/secretory product is capable of inducing specific-protective immunity against infection of a host by a second parasitic nematode species which may be the same as or different from the first nematode

species. Therefore, the immunity protection is highly specific. Also at column 6, lines 57-58, the reference teaches that the disclosed product has a molecular weight less than 12 Kd (kilodaltons) and hence is identical to the claimed product.

Furthermore, Applicants' claims do not require suppression of immunity per se. In addition, the claimed product is drawn to being capable of inducing apoptosis in reactive T-cells which is also high specific with respect to Applicants' argument regarding suppression of immunity. Also the reference does not provide disclosure of the protective immunity being induced to be related to presence of reactive T-cells. Therefore, the argument that the reference is not valid because of its teaching of being capable of inducing protective immunity against parasitic nematodes is not persuasive. Applicants' argument regarding the critical claimed feature of inducing apoptosis in reactive cells does not change the composition they are claiming of which is clearly anticipated by the excretory/secretory product of the cited reference.

It has the same molecular weight and is derived from the same microorganism: *Necator americanus*. The induction of apoptosis in reactive T-cells is an inherent feature of the same product disclosed by the cited reference. Therefore, even though the critical claimed feature is not disclosed Applicants have provided no evidence that the disclosed composition does not possess the characteristic of inducing apoptosis in reactive T-cells. It should be noted that protective immunity is a complex process and the mere fact that the cited disclosure teaches inducing it against parasitic nematodes is not evidence that the disclosed product can not induce apoptosis in reactive T-cells.

All of the claim features and elements are clearly disclosed in a single reference, as cited herein, with respect to the composition and what it actually comprises, per se. The argument that under principles of inherency the single reference must necessarily function within the limitations of the claims is noted, however, the claims do not necessarily omit inducing specific protective immunity against another nematode. The examiner is persuaded that the claimed product also can function by inducing protective immunity against another nematode as disclosed by the reference. Applicants have the burden of presenting evidence to the contrary which thus far they have provided no evidence on the record. The arguments that have been presented to date are not considered to be evidence and hence the rejection is being maintained.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

All claims fail to be patentably distinguishable over the state of the art discussed above. Therefore, the claims are properly rejected.


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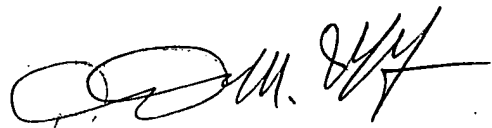
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Deborah K. Ware  
December 9, 2005

  
DAVID M. NAFF  
PRIMARY EXAMINER  
ART UNIT 12651